

August 23, 1999

**VETERINARY SERVICES MEMORANDUM NO. 800.87**

Subject: Guidelines for Licensing Establishments with Separated Premises

To: Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics

**I. PURPOSE**

This memorandum provides guidance for licensing two or more remotely located premises as one establishment under the provisions of 9 CFR 102.4.

**II. CANCELLATION**

This memorandum cancels Veterinary Biologics Memorandum No. 800.87 dated May 14, 1996.

**III. GENERAL**

The regulations in 9 CFR 102.4 prohibit the Animal and Plant Health Inspection Service (APHIS) from issuing an establishment license unless, in the opinion of the Administrator, the establishment can be operated in compliance with the Virus-Serum-Toxin Act (VSTA). The regulations in 9 CFR 115 authorize APHIS inspectors to inspect licensed facilities and products to determine whether they comply with the VSTA and regulations. It has been APHIS policy to inspect all premises of an establishment that are used for preparation, testing, and initial shipment at one time. When premises separated by too great a distance are listed on the same establishment license, there may be problems in carrying out these inspections. These guidelines establish criteria for documenting activities and maintaining records to address these problems and permit APHIS to inspect under such conditions.

**IV. GUIDELINES**

APHIS will consider the licensing of two or more remotely located premises as one establishment under the following conditions:

A. Responsibility for Operations

Each licensed establishment must have one person legally responsible for all activities at all premises listed on the establishment license.

B. Mailing Address

The licensed establishment should have one mailing address for all government correspondence.

C. Government Liaison

Each licensed establishment must have one government liaison representing all premises listed on the establishment license. This liaison should handle all government submissions and correspondence and coordinate inspection activities and compliance. If a premises is beyond a reasonable travel time from the normal location of the liaison, the licensee may designate an alternate liaison to coordinate compliance and unannounced inspections at that premises.

D. Serial Release

One person representing the licensed establishment should be responsible for control of final serial release. APHIS will report serial releases for all products to that person at one address.

E. Records

All premises listed on the establishment license should use the same system to maintain and retain records. This includes the record keeping system for serial assembly and subsequent handling. The licensee should maintain the original copies of records for inspection at the premises where the activity occurs.

F. Official Documents

The licensee must maintain appropriate plot plans, blueprints, legends, outlines, and other official documents at each premises for use by APHIS inspectors. A copy of the current approved document is acceptable.

G. Movement of Biological Materials Between Premises

The plot plan legend should describe how materials move between premises. The materials include component parts to be combined to form a biological product, all biological products in the course of preparation, and all completed biological products. Also describe the precautions taken to protect such materials during movement between premises. Firms should identify and describe the mode of transportation for such materials in the plot plan legend as they would describe a piece of equipment such as a cooler. The Veterinary Services Memorandum No. 800.87

plot plan legend should also describe how such materials move between the mode of transportation and the production or in-process cooler. Firms should revise their plot plan legends as necessary to ensure that they include all such materials being moved and all new or revised procedures being used.

#### H. Transfer Documents

Firms must use transfer documents to certify that they are following the procedures established to ensure product protection during movement between premises. The records should show how and when periodic checks are conducted on refrigeration equipment and temperature recording devices used in such transfers to ensure proper temperatures are being maintained.

#### I. Licensing Documents

Within one year of the date when premises previously licensed as separate establishments are consolidated and licensed as one establishment, the firm must resubmit official outlines, labels, plot plans, legends, blueprints, and other documents to reflect the change.

### **V. EXCEPTIONS**

Premises previously exempted from appearing as production facilities on establishment licenses are not subject to this memorandum. Examples of such premises are irradiation facilities and milk collection and assembly points.

/s/

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Veterinary Services